UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re NURTURE BABY FOOD LITIGATION This document relates to: ALL ACTIONS	Case No. 1:21-cv-01217-MKV

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO STRIKE THE DECLARATION OF NEGA BERU SUBMITTED IN SUPPORT OF DEFENDANT NURTURE, LLC'S MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

PRELIMINARY STATEMENT AND RELEVANT FACTS

Plaintiffs submit this Memorandum of Law in support of their motion to (1) strike all or portions of the Declaration of Nega Beru, Ph.D ("Beru Declaration") (Dkt. 165) submitted by Defendant Nurture, LLC ("Defendant" or "Nurture") in support of its Motion to Dismiss ("MTD") Plaintiffs' Consolidated Class Action Complaint ("CC") (Dkt. 163) or, in the alternative, (2) disregard the Beru Declaration in its entirety, in considering the MTD.

While matters outside the pleadings may sometimes be considered on a primary jurisdiction motion, the Beru Declaration is not a matter that can or should be considered here. Dr. Beru's testimony should not be judicially noticed under Fed. R. Evid. 201 because: it (1) was not attached to or referenced in the CC; and (2) is not sufficiently probative of or integral to the issue of primary jurisdiction. The Beru Declaration was created by an industry lobbyist, at Nurture's request, for an undisclosed sum of money, based on undisclosed materials, none of which materials are judicially noticeable. The Beru Declaration should also be stricken or disregarded because it: (1) contains improper lay testimony under Fed. R. Evid. 701 that is both speculative and argumentative; and (2) is inadmissible premature, unqualified, and unreliable expert witness testimony under Fed. R. Evid. 702 and inadequate under Fed. R. Civ. P. 26(b)(2)(B).

Dr. Beru is a presumably a paid expert and "hired gun" for the baby food industry. In 2017, Dr. Beru left his position at the Food and Drug Administration ("FDA"). This shows that Dr. Beru's testimony is replete with obvious speculation about what the FDA is or is not doing presently about heavy metals in baby foods and what the FDA may or may not do in the future. This testimony is speculative, immaterial, and inadmissible that is prejudicial to Plaintiffs who have no opportunity to cross examine or depose Dr. Beru. For these reasons, Dr. Beru's testimony is both improper and unreliable and should be stricken from the record.

The Beru Declaration also purports to offer unsurprising and self-serving opinions about the safety of heavy metals in baby foods. Dr. Beru is not a qualified expert in this case and his declaration fails to even meet the most basic of standards required under the Federal Rules. Critically, Nurture's primary jurisdiction argument rests on its mischaracterization of this case as one about "safety" and action levels. (*i.e.*, safe levels of heavy metals and perchlorate in Nurture's baby food) (*see* Dkt. 165 at pages 20–29). But this is a classic consumer protection case concerning misleading packaging alleging only economic harm - action levels will not determine liability here. This fact alone shows the Beru Declaration - and its conclusory, and hypothetical statements - should not be considered by the Court.

Attached to the Declaration of Lori G. Feldman ("Feldman Decl.") as Exhibit A is a chart detailing the portions of the Beru Declaration the relevant objections thereto.

LEGAL STANDARDS

In determining whether to consider or take judicial notice "[o]n a motion to dismiss, 'the Court is entitled to consider facts alleged in the complaint and documents attached to it or incorporated in it by reference, documents "integral" to the complaint and relied upon in it.'" *Purdie v. Brown*, 2015 WL 6741875, at *3 (S.D.N.Y. Nov. 3, 2015) (quoting *Heckman v. Town of Hempstead*, 568 F. App'x 41, 43 (2d Cir. 2014)). "For a document to be considered integral to a complaint, a plaintiff must 'rel[y] on the terms and effect of [the] document in drafting the complaint . . .; mere notice or possession is not enough.'" *Id*. (quotation omitted).

In this Circuit, "a court may . . . strike portions of an affidavit that are not based upon the affiant's personal knowledge, contain inadmissible hearsay or make generalized and conclusory statements." *Hollander v. Am. Cyanamid Co.*, 172 F.3d 192, 198 (2d Cir. 1999)). It is also within a court's discretion to strike an affidavit that "resemble[s] an adversarial memorandum [more] than a bona fide affidavit", (*id.*) or "simply decline to consider those aspects of a supporting affidavit

that do not appear to be based on personal knowledge or are otherwise inadmissible." *Doe v. Nat'l Bd. of Podiatric Med. Examiners*, 2004 WL 912599, at *4 (S.D.N.Y. Apr. 29, 2004); *see also* Fed. R. Evid. 701 (improper lay testimony); 602 (lack of personal knowledge); 702 (improper expert testimony); 802 (improper hearsay).

ARGUMENT

I. THE BERU DECLARATION SHOULD NOT BE CONSIDERED

A. The Beru Declaration is Not Subject to Judicial Notice

The Beru Declaration is not integral to the CC. It was created at the behest of defense counsel by a former FDA employee who left the FDA many years ago and who claims to, but cannot possibly have personal knowledge of the FDA's ***present day*** and future work in response to the Subcommittee of Economic and Consumer Policy of the U.S. House of Representatives' Oversight and Reform Committee issued a staff report on February 16, 2021 (the "Report") (issued four years after Dr. Beru left the agency). Nor does the CC cite to the Beru Declaration. Instead, the Beru Declaration is replete with inadmissible hearsay that should not be judicially noticed or considered by this Court. *See, e.g.*, *Hollander*, 172 F.3d at 198 (refusing to consider affidavit); *Casey v. Odwalla*, Inc., 338 F. Supp. 3d 284, 289 (S.D.N.Y. 2018) (refusing to take judicial notice of or give preemptive effect to FDA materials on a motion to dismiss).

B. The Beru Declaration is Improper Witness Testimony

1. The Beru Declaration is Improper Lay Witness Testimony

Federal Rule of Evidence 701, as amended December 19, 2022, provides that lay witness opinion testimony "is limited to one that is "(a) rationally based on a witness's perception" and (b) "helpful to clearly understanding the witness's testimony or to determining a fact in issue." The burden is on the party wishing to introduce lay opinion testimony to establish the proper foundation." *United States v. Grinage*, 390 F.3d 746, 749 (2d Cir. 2004).

The lay opinions in the Beru Declaration do not meet the foundational standards required by Rule 701. His opinions are speculative and not helpful to the determination of a fact issue. Defendant fails to identify whether Dr. Beru's testimony is being offered as lay opinion, expert opinion, a combination of the two, or something else entirely. While Defendant cites to the Beru Declaration seven times in its supporting MTD brief (Dkt. 163, at pages 4, 21, 22, 24, 25), it does not explain why Dr. Beru's testimony is even warranted given that the FDA's Closer to Zero Plan is already a matter of public record. Plaintiffs were not notified in advance that Dr. Beru would be providing testimony, nor were they afforded the opportunity to seek discovery from him, depose and cross examine him, or even obtain the most fundamental information from him or about the "materials" that he testifies that he reviewed and relied upon in preparing his declaration. Nor did Plaintiffs rely on Dr. Beru's testimony in the CC.

Given that many of Dr. Beru's opinions are speculative, they do not meet Rule 701's requirement that the opinion be helpful to an issue of fact. Primary jurisdiction is an issue of law, not fact, and this is a pleading motion. *See Segedie v. The Hain Celestial Grp., Inc.*, 2015 WL 5916002, at *2 (S.D.N.Y. Oct. 7, 2015) ("preemption, primary jurisdiction, and exhaustion of administrative remedies are 'pure questions of law' that the reviewing court could decide without knowledge of the record.") The speculative facts offered by Dr. Beru are simply not helpful or needed and should be stricken from the record or disregarded.

Dr. Beru testifies that he retired from the FDA in 2017. (Dkt. 165, ¶¶ 2, 3). Notwithstanding his claim to the contrary, Dr. Beru could not possibly have personal knowledge of the day-to-day work being done and the relevant specifics of the FDA's Closer to Zero Plan ("FDA's Future Plans") since he has not worked at the FDA for years. The FDA's Future Plans

did not begin until well *after* the Report was issued in 2021 – *four years after Dr. Beru left his post at the FDA.*

Nor is there any need for Dr. Beru to "opine" on the nature of the FDA's Future Plans or to characterize them as an "extraordinary mobilization" of resources, an "enormous undertaking," or standing out "for the level of targeted attention and expenditure of resources FDA is devoting to this specific food safety issue *at this time*." (Dkt. 165, ¶ 9 (emphasis added).) His characterizations are also undermined by major problems at the FDA in the wake of the infant formula crisis in 2022. These significant and material problems were recently the subject of a report from the Reagan-Udall Foundation for the FDA, which the agency asked to assess its operations. The "scathing report" urges "major changes" at the FDA, including possibly breaking up the agency. *The Washington Post, December 6, 2022* ("the agency has been under pressure for nearly a year to overhaul its food program, partly because of an infant formula crisis") (copy attached as Exhibit B to the Feldman Decl.; the full report is attached as Exhibit C to the Feldman Decl.). The FDA did not have the resources to adequately handle the infant formula crisis, a crisis that occurred only *after* the FDA was left scrambling to get a handle on the heavy metals in baby food problems. Notably, Dr. Beru was not at the FDA during either of these crises and has no personal knowledge to have the most basic foundation to opine on these unprecedented events.

Moreover, the FDA's former Associate Commissioner for Foods and Chief Medical Officer at the FDA's food center believes that, with respect to heavy metals, the FDA's response has typically been one of "putting out fires" rather than implementing a fundamental strategic plan." As to the metal content in baby food, Dr. Acheson has said that the FDA has "known all

along that it is a risk."[1] If anything, given the catastrophic level of problems that the FDA cannot adequately handle at present, and likely in the mid- to- long term future, it is highly unlikely that the FDA will be able to properly address the heavy metals in baby foods issues any time soon. This supports Plaintiffs' position that the Court – rather than the FDA – is best suited to address the consumer protection claims (*i.e.*, that the baby food is misleadingly packaged) raised in this litigation. The Beru Declaration is simply not relevant, material, or credible. This Court and others within the Second Circuit have consistently held that cases requiring a determination of whether product labeling is deceptive or misleading to a reasonable consumer is "a question which courts are 'eminently well suited' to entertain." *Goldemberg v. Johnson & Johnson Consumer Companies, Inc.*, 8 F. Supp. 3d 467, 476–77 (S.D.N.Y. 2014). As a result, the Beru Declaration should not be considered in connection with the MTD.

2. The Beru Declaration Is Improper Expert Testimony

Under Fed. R. Evid. 702(a), only a witness "who is qualified as an expert by knowledge, skill, experience, training, or education" may furnish opinion testimony, and only if, *inter alia*, "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue[.]"In his declaration, Dr. Beru holds himself out as an expert on public health policy and regulatory issues, having "served as the Director of the Office of Food Safety in FDA's food safety and Applied Nutrition (CFSAN)" from 2006 to December 2017. (Dkt. 165, ¶ 3) As a Director of Food Safety, Dr. Beru "oversaw the development and issuance of several regulations as well as guidelines for industry." (CV of Nega Beru, Ph.D.,

[1]https://news.bloomberglaw.com/interactive/baby-foods-with-toxic-metals-stay-on-us-market-while-fda-dithers (last accessed on January 5, 2023).

Exponent, Engineering & Scientific Consulting, Washington, D.C.; Dkt. 165-1 at page 2); Beru Declaration at ¶ 4 (Dkt. 165, page 2).) Dr. Beru provides opinions regarding the FDA's mandates (¶¶ 4-5), the safety of heavy metals in baby foods (¶¶ 5-6), CFSAN's work, (¶¶ 4, 18), FDA's monitoring of heavy metals (¶¶ 5-10), the nature and extent of FDA resources, ¶¶ 7-18), scientific and technical challenges of heavy metals in the food supply (¶ 7-18), the FDA action plan approval process (¶ 8-18), FDA stakeholder interaction (¶ 15), global heavy metal issues (¶ 16), and what the FDA is presently doing to make food safe in light of heavy metals in foods (¶ 17-18). Dr. Beru has not, however, been identified as an expert witness by Nurture, nor has Nurture complied with any of the other expert disclosure mandates under Fed. R. Civ. P. 26(a)(2). The Beru Declaration is premature and untimely expert opinion and should not be considered by the Court.

Federal Rule of Civil Procedure 26(a)(2) mandates the pretrial disclosure of the identities of expert witnesses, as well as other related information such as their opinions. To prevent the unfair "sandbagging" of adverse parties, Rule 37(c)(1) prohibits the use of expert opinions that were not timely disclosed under Rule 26(a)(2). *See United States v. City of N.Y*, 2010 WL 2838386, at *2 (E.D.N.Y. July 19, 2010) (precluding testimony of witness who was not timely identified as an expert witness). Fed. R. Civ. P. 37(c)(1) states that "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1).

It is undisputed that Nurture did not disclose Dr. Beru as an expert under Rule 26(a)(2). Nurture has no adequate justification for its request that the Court consider the Beru Declaration which would prejudice Plaintiffs. Indeed, Plaintiffs did not have proper notice or an opportunity to retain rebuttal experts or depose Dr. Beru. *See* Fed. R. Civ. P. 37(c)(1). If the Court believes

that Plaintiffs should be afforded the right to obtain all documents considered by Dr. Beru in his analysis and depose Dr. Beru, their counsel welcomes that opportunity prior to the Court's ruling on the MTD, and be afforded the right to supplement Plaintiffs' opposition to MTD after taking Dr. Beru's deposition. Otherwise, the Beru Declaration should be stricken from the record and/or disregarded by the Court. Finally, if the Court does take judicial notice of the Beru Declaration, it should not consider the truth of Dr. Beru's statements or consider any disputed facts set forth in his declaration.

3. The Objectionable Paragraphs

Exhibit A to the Feldman Decl. is a chart detailing the portions of the Beru Declaration that Plaintiffs find objectionable, together with the basis of such objections. For the reasons set forth herein and in Exhibit A, Plaintiffs respectfully request that the Court strike and/or disregard the entire Beru Declaration (including Dr. Beru's CV) or, in the alternative, paragraphs 4 through 18 thereof. Alternatively, Plaintiffs ask the Court to afford them the right to discovery (including but not limited to Dr. Beru's deposition) as to the Beru Declaration and his testimony therein.

CONCLUSION

Plaintiffs respectfully request that the Court strike the Beru Declaration in its entirety. In the alternative, Plaintiffs respectfully request the Court refuse to consider the declaration in deciding the pending motion to dismiss.

Dated: January 5, 2023
New York, New York

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